4EHP-81-394

May 15, 1998

Committee No CB

BY CERTIFIED MAIL

Document Processing Center (7407)
Attn: Section 8(e) Coordinator
Office Of Toxic Substances
United States Environmental Protection Agency
401 M Street, Southwest
Washington, D. C. 20460



Re:

TSCA Section 8(e) -- Perfluorooctane Sulfonate -- Docket Numbers 8EHQ-1180-373; 8EHQ-1180-374; 8EHQ-0381-0394

Dear Sir/Madam:

With this letter, 3M Company is submitting information to the EPA Administrator pursuant to Section 8(e) of the Toxic Substances Control Act ("TSCA"). As detailed below, this information relates to fluorochemicals -- specifically, perfluoroctane sulfonate ("PFOS") [CAS No. 2795-39-3] -- and consists of analysis of blood sera samples showing PFOS at very low (i.e., parts per billion ("ppb")) levels. The presence of organic fluorochemicals in the blood of the general population and subpopulations, such as workers, has been known dating back to the 1970's, and 3M's epidemiological study of its own workers indicates no adverse effects at parts per million levels. 3M does not believe that any reasonable basis exists to conclude that PFOS "presents a substantial risk of injury to health or the environment." Nevertheless, as a precautionary measure, 3M is submitting this information to the TSCA Section 8(e) docket at this time.

See, e.g., Taves, D.R.; Comparison of "Organic" Fluoride in Human and Nonhuman Serums, 50 J. Dent. Res. 783 (1971); Guy, W.S., et al.; Biochemistry Involving Carbon Fluorine Bonds, American Chemical Society, 117-34 (1976); Ubel, F.A., et al.; Health Status Of Plant Workers Exposed to Fluorochemicals -- A Preliminary Report, 4 American Indus. Hygiene J. 584 (Aug. 1980). 3M has submitted PFOS-related medical surveillance and epidemiological information on its own production workers as well as animal toxicology data previously to the TSCA Section 8(e) docket. See Docket Numbers 8EHQ-1180-373; 8EHQ-1180-374; 8EHQ-0381-0394

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In the process of validating analytical methodology for measuring PFOS, a product of the electrochemical fluorination process, an outside laboratory detected PFOS at ppb levels in blood samples from individuals with no known occupational exposure to fluorochemicals. Subsequent analyses of commercially pooled sera from human blood bank samples in different regions of the United States measured PFOS levels between 9 ppb and 56 ppb.² Analyses of limited historical blood samples from 1969 and 1976 showed mean PFOS levels of 28 ppb and 33 ppb, respectively. Analyses of limited animal sera samples found comparable PFOS levels. 3M also has conducted qualitative *in vitro* and *in vivo* metabolism studies, which suggest the possibility that non-occupational presence of PFOS could result from the metabolic conversion of other fluorochemicals to PFOS.

3M would welcome the opportunity to discuss our findings and our plans. We are sending a copy of this letter to Charles Auer, Director of the Chemical Control Division, and will be contacting him shortly to arrange a meeting for this purpose. In the meantime, please do not hesitate to contact William Weppner at (612) 733-6374 with any questions.

Sincerely,

Dr. Charles Reich Group Vice President Chemical Markets Group

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³M also analyzed these sera samples for another fluorochemical -- perfluoroctanoate ("PFOA") [CAS No. 3825-26-1] -- but detected the presence of PFOA at quantifiable levels of 12 and 22 ppb in only two of the samples.